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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/173,463	10/14/98	BLACK M	240052.429

HM12/0307

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EXAMINER	
FRONDA,C	
ART UNIT	**PAPER NUMBER**
1652	5

DATE MAILED: 03/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/173,463	Black
Examiner	**Group Art Unit**
Christian L. Fronda	1652

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-60* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-60* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to an isolated nucleic acid encoding a *Herpesviridae* thymidine kinase enzyme and an expression vector, classified in class 435, subclass 320.1.

II. Claims 16-30, drawn to an isolated nucleic acid molecule encoding a fusion protein comprising a guanylate kinase moiety and a thymidine kinase moiety, and a vector, classified in class 435, subclass 320.1.

III. Claims 31-41, drawn to an isolated *Herpesviridae* thymidine kinase enzyme, classified in class 435, subclass 183.

IV. Claims 42-50, drawn to a fusion protein comprising a guanylate kinase moiety and a thymidine kinase moiety, classified in class 435, subclass 183.

V. Claims 51-60, drawn to a method of inhibiting a pathogenic agent in a warm-blooded animal, a pharmaceutical composition, and a method for monitoring the progress of gene therapy in a subject, classified in class 435, subclass 7.72 .

2. The inventions are distinct, each from the other because of the following reasons:

The DNA of group I is related to the thymidine kinase enzyme of group III by virtue of the fact that the DNA codes for the enzyme. The DNA molecule has utility for the recombinant

production of the enzyme in a host cell. Although the DNA and the enzyme are related, since the DNA encodes the specifically claimed enzyme, they are distinct inventions because the enzyme can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of the enzyme, such as nucleic acid hybridization assays.

The DNA of group II is related to the fusion protein of group IV by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the fusion protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of the protein, such as nucleic acid hybridization assays.

Each of groups I and IV is directed to a separate and distinct invention. Group I is directed toward to an isolated nucleic acid encoding a *Herpesviridae* thymidine kinase enzyme and an expression vector; and group IV is directed toward a fusion protein comprising a guanylate kinase moiety and a thymidine kinase moiety. The products of groups I and IV, respectively, would be expected to have distinct functional, chemical, and physical properties. These products are capable of separate manufacture, use, or sale, and are patentable over each other.

Each of groups II and III is directed to a separate and distinct invention. Group II is directed toward to an isolated nucleic acid encoding a fusion protein comprising a guanylate kinase moiety and a thymidine kinase moiety, a viral vector, and a pharmaceutical composition; and group III is directed toward a *Herpesviridae* thymidine kinase enzyme. The products of groups II and III, respectively, would be expected to have distinct functional, chemical, and physical properties. These products are capable of separate manufacture, use, or sale, and are patentable over each other.

Each of groups I and II is directed to a separate and distinct invention. Group I is directed toward to an isolated nucleic acid encoding a *Herpesviridae* thymidine kinase enzyme and an expression vector; and group II is directed toward to an isolated nucleic acid encoding a fusion protein comprising a guanylate kinase moiety and a thymidine kinase moiety, a viral vector, and a pharmaceutical composition. The products of groups I and II, respectively, would be expected to have distinct functional, chemical, and physical properties. These products are capable of separate manufacture, use, or sale, and are patentable over each other.

Each of groups III and IV is directed to a separate and distinct invention. Group III is directed toward a *Herpesviridae* thymidine kinase enzyme; and group IV is directed toward a fusion protein comprising a guanylate kinase moiety and a thymidine kinase moiety. The products of groups III and IV, respectively, would be expected to have distinct functional, chemical, and physical properties. These products are capable of separate manufacture, use, or

sale, and are patentable over each other.

Each of groups III and V is directed to a separate and distinct invention. Group III is directed toward a *Herpesviridae* thymidine kinase enzyme; and group V is directed toward a method of inhibiting a pathogenic agent in a warm-blooded animal. The product described in group III and process described in groups V do not require each other for their practice. The product and processes are distinct both physically and functionally; require different process steps, reagents, and parameters; produce different products; and are subject to separate manufacture and sale from each other.

Each of groups IV and V is directed to a separate and distinct invention. Group IV is directed toward a fusion protein comprising a guanylate kinase moiety and a thymidine kinase moiety; and group V is directed toward a method of inhibiting a pathogenic agent in a warm-blooded animal. The product described in group IV and processes described in group V do not require each other for their practice. The product and processes are distinct both physically and functionally; require different process steps, reagents, and parameters; produce different products; and are subject to separate manufacture and sale from each other.

Each of groups I and V is directed to a separate and distinct invention. Group I is directed toward an isolated nucleic acid encoding a *Herpesviridae* thymidine kinase enzyme and an expression vector; and group V is directed toward a method of inhibiting a pathogenic agent in a warm-blooded animal. The product described in group I and process described in group V do

not require each other for their practice. The product and process are distinct both physically and functionally; require different process steps, reagents, and parameters; produce different products; and are subject to separate manufacture and sale from each other.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as using specific antibodies or antibiotics to inhibit a pathogenic agent in a warm-blooded animal.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the isolated nucleic acid in an expression system to produce thymidine kinase enzyme.

For these reasons restriction for examination purposes is proper.

3. A telephone call was made to David D. McMasters on March 2, 2000, to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF
March 2, 2000

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600